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§21–2B–02.

(a) A manufacturer of an investigational drug, biological product, or device may:

(1) Provide the manufacturer's investigational drug, biological product, or device to an eligible patient without compensation; or

(2) Subject to subsection (b) of this section, require an eligible patient to pay the costs of or associated with the manufacture of the investigational drug, biological product, or device provided to the eligible patient.

(b) (1) Any payment required by a manufacturer under subsection (a)(2) of this section shall be limited to the recovery of the costs of or associated with the manufacture of the specific investigational drug or biological product dosages or devices provided to the eligible patient.

(2) A manufacturer of an investigational drug, biological product, or device may not profit from providing an investigational drug, biological product, or device provided to an eligible patient.

(c) After the date that an eligible patient begins taking or using the investigational drug, biological product, or device and during the time the eligible patient is taking or using the investigational drug, biological product, or device, the manufacturer shall notify the eligible patient and the eligible patient's health care provider of any side effects or risks associated with the investigational drug, biological product, or device that are required to be disclosed to the United States Food and Drug Administration during the drug approval process.

(d) (1) The Office of the Attorney General shall develop an informed consent form that:

(i) Complies with the requirements of § 21–2B–01(e)(3) of this subtitle;

(ii) Includes instructions for the physician or patient on how to complete the form; and

(iii) Provides spaces for a physician to include the information relating to a particular patient and the physician's recommendation for the patient.

(2) This subsection may not be construed to prohibit a treating physician or a manufacturer of an investigational drug, biological product, or device from including additional information or advisements with the informed consent form developed under paragraph (1) of this subsection.

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